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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,643	01/26/2004	Axel F. Brisken	017148-003630US	1201

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EXAMINER	
SHAHRESTANI, NASIR	
ART UNIT	**PAPER NUMBER**
3737	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/765,643	BRISKEN ET AL.	
	Examiner	Art Unit	
	Nasir Shahrestani	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *26 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/29/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenschein (U.S. Patent No.: 5,836,896) in view of Alten et al. (Non-Patent Literature Article) and in further view of Claren et al. (U.S. Patent No.: 6,524,333).

Regarding claims 1-2, 4, 6-7, 10, 13, 15, 17-18, Rosenschein discloses an invasive ultrasonic device (fig. 3) and method for inhibiting restenosis, and therefore treating an arterial stenosis, by destroying unwanted cells (see abstract; column 11 lines 26-60). Furthermore, Rosenschein discloses implanting a scaffold structure (claim 16). Rosenschein does not specifically disclose a method for using the device for inhibiting neointimal hyperplasia. Alter et al. discloses a method of using ultrasound energy to treat smooth muscle cell migration and cell proliferation leading to intimal hyperplasia. Although alter et al. does not specifically mention the method for inhibiting neointimal hyperplasia, the disclosed method however would obviously inhibit neointimal hyperplasia because a target site would inherently not be at risk of neointimal hyperplasia. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the method as taught by Rosenschein and to have further included the aforementioned method as taught by Alter et al. and it would have been obvious to destroy

unwanted cells at a desired range, including at a desired mechanical index for a desired period of time (see Rosenschein, column 11 lines 56-60), in order to inhibit the growth of unwanted cells, thus allowing re-endothelialization of a neointimal in an injured artery. However, Rosenschein in view of Alter et al. does not teach the scaffold structure being coated with a pharmaceutical agent which is released into the site over time after exposure to vibrational energy (e.g. ultrasound). Claren et al. teaches a scaffold structure coated with a pharmaceutical agent, which is released at vibration (column 3 lines 9-12). It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the method as taught by Rosenschein in view of Alten et al. and to have further included the aforementioned step as taught by Claren et al. to allow repeated therapeutic treatment of the blood vessel, which preferably is effected during the first six weeks after insertion of the scaffold and to prevent growth of biological material onto the scaffold (Claren et al., column 3 lines 15-35).

Regarding claims 3, 5, 8-9, 11-12, 14, 16, Rosenschein teaches frequencies in the range of 10 kHz –5Mhz and wherein the vibrational energy is kept at a level that would cause minimal cavitation in a wall of the blood vessel and remain viable but in a quiescent state (column 10 lines 49-61) and inherently having a duty cycle between 0.1 and 100 percent. Furthermore Rosenschein teaches the use of intensities sufficient to create acoustic transient cavitation at the locus of therapy (column 11 lines 63-67) and therefore it would have been obvious to one of ordinary skill in the art to have provided to have various ranges of sufficient intensity.

Regarding claims 19-20, Rosenschein further teaches a non-invasive ultrasound technology that enables directing vibrational energy transcutaneously to the vascular treatment site and focusing an externally generated acoustic beam (column 11 lines 63-67, column 12 lines 1-6).

Claims 21 & 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenschein (U.S. Patent No.: 5,836,896) in view of Alten et al. (Non-Patent Literature Article) and in further view of ~~and in further view of~~ Carter (U.S. Patent No.: 5,362,309).

Rosenschein in view of Alten et al. teaches all the limitations of claim1 as described above but does not teach the use of anti-coagulants such as heparin being a nucleic acid sequence. Carter teaches a composition having activity for the inhibition of restenosis using heparin (column 2 lines 34-41). It would have been obvious to one of ordinary skill at the time of the invention to have modified the method as taught by Rosenschein in view of Alten et al. and to have further included the aforementioned step as taught by Carter in order to enhance the delivery of restenosis inhibiting drugs into the vascular wall.

Claims 22-23, 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenschein (U.S. Patent No.: 5,836,896) in view of Alten et al. (Non-Patent Literature Article) and in further view of Jacobs et al. (U.S. Pub. No.: 2001/0016650).

Rosenschein in view of Alten et al. teaches all the limitations of claim1 as described above but does not teach wherein the pharmaceutical agent comprises a nucleic acid sequence comprising thymidine kinase, nor does it teach the pharmaceutical agent being dispersed in a

biodegradable matrix comprising polylactic acid applied to the surface of the scaffold structure. Jacobs et al. teaches the treatment of restenosis using 3H-Thmidine (par. [0190]) and antisense constructs, and also teaches choices of matrix materials comprising polylactic and polyglycolic acids (par. [0213]). It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the methods as taught by Rosenschein in view of Alten et al. and to have further included the use of the aforementioned constructs as taught by Jacobs et al. in order to prevent restenosis while providing biodegradability while increasing uptake values.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nasir Shahrestani whose telephone number is 571-270-1031. The examiner can normally be reached on Mon.-Thurs: 7:30-5:00, 2nd Friday: 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nasir Shahrestani
11/17/2006

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